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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,892	08/20/2003	Michael C. Bednarek	11531US.01	8201

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EXAMINER	
PEFFLEY, MICHAEL F	

ART UNIT	PAPER NUMBER
3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,892	BEDNAREK, MICHAEL C.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-16 and 18-33* is/are pending in the application.

4a) Of the above claim(s) *25 and 27-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-16,18-24,26,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 Aug 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's amendments and comments, received May 15, 2009, have been fully considered by the examiner. The following is a complete response to the May 15, 2009 communication.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3-13, 15, 16, 18 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Brucker et al (5,643,197).

As shown in Figures 15 and 16, Brucker et al disclose an ablation catheter that has a fixed braided electrode (91 – col. 8, lines 10-14) mounted on a catheter shaft (22) between an inner tubular surface and the outer catheter surface (see Figure 16). An aperture is created along the length of the electrode whereby the electrode is exposed to tissue (see Figures 15 and 16). Brucker et al further disclose a lumen (28) for providing fluid through the catheter, as well as apertures in the inner surface of the catheter shaft to allow the fluid to pass through the braided electrode surface (col. 8, lines 42-57). The length of the electrode is up to about 5 cm (col. 8, line 63), and the examiner maintains the device is inherently capable of moving blood away from the

electrode via the fluid flow and capable of treating tissue in the same manner (i.e. ohmic heating, convection) suggested by applicant's various recitations of intended use.

Claims 3-16, 18, 26 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Collins et al (6,837,886).

Collins et al disclose an ablation catheter comprising a fixed braided electrode (28) for forming an ablation lesion. As shown in Figure 20E, the ablation electrode is encapsulated (i.e. between inner and outer walls) in a shroud (137). A plurality of openings (139) are provided to allow the exposed portions of the braided electrode to come into contact with tissue (col. 14, lines 25-33). Collins et al also disclose providing a fluid through the braided electrode member (col. 13, lines 65-67) by directing the irrigant with the shroud member. Collins et al disclose the use of a conductive irrigant, and the Collins et al device is deemed to operate to treat tissue in the same manner (e.g. ohmic heating, convection, conduction, etc.) as recited in applicant's claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-13, 15, 16, 18, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al (6,078,830) in view of the teaching of Brucker et al ('197).

Levin et al disclose an ablation catheter that includes a catheter shaft (26) having an inner and outer surface and an electrode (50,52,54) fixed between the inner and outer surfaces of the catheter wall (see Figures 3 and 4). The electrode also extends slightly above the outer surface of the electrode as shown in these figures, the section of the exposed electrode occurring at an aperture portion of the catheter body. Levin et al fail to specifically disclose the use of a braided electrode, and also fail to disclose a fluid passage lumen for providing a fluid to/through the electrodes.

The examiner maintains that it is generally known in the art to substitute various electrode configurations, such as helical, mesh or braided structures. Brucker et al, as addressed above, disclose various flexible electrode structures, and specifically teach that it is known to embed a braided electrode mesh into a catheter wall. Additionally, Brucker et al teach that it is known to provide fluid apertures in the catheter wall in communication with a central lumen for providing a fluid to and through the electrodes located in the catheter wall.

To have provided the Levin et al device with braided electrodes is deemed an obvious design consideration for one of ordinary skill in the art since Brucker et al fairly teach it is known to embed braided electrodes in the wall of a catheter in an analogous device. additionally, it would have been obvious to have provided the Levin et al catheter with a fluid passage and aperture To direct the fluid to the electrodes to allow flushing of the electrode since Brucker et al teach that it is known to provide such a perfusion means in an analogous device.

Claims 14 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al ('830) and Brucker et al ('197) as applied to the claims above, and further in view of the teaching of Collins et al ('886).

Levin et al and Brucker et al both disclose the exposed electrode portion on the catheter extends around the circumference of the catheter. There is no express teaching of providing an aperture that has a limited window around the circumference of the catheter.

As addressed above, Collins et al disclose another catheter device that has a braided electrode member embedded in the wall of a catheter. Collins et al teach that the embedded electrode may be exposed around the entire circumference of the catheter (Figures 20A, 20B, 20C), or alternatively that the electrode may be exposed at selected portions (Figure 20E) to control the delivery of energy to tissue. The examiner maintains that providing the apertures in any desired spacing and/or size would be an obvious design modification for one of ordinary skill in the art.

To have provided the Levin et al device, as modified by the teaching of Brucker et al, with electrode apertures of a limited range to control the delivery of energy to tissue would have been an obvious design modification for one of ordinary skill in the art in view of the teaching of Collins et al.

Claims 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al ('830) and Brucker et al ('197) as applied to the claims above, and further in view of the teaching of Bednarek et al (6,120,500).

Levin et al and Brucker et al fail to disclose a secondary lumen carrying a control wire for shaping the catheter body as recited in these claims.

As addressed in the previous Office action, Bednarek et al discloses another ablation catheter that provides a second lumen (23 - Figure 11) including a control wire (16) for providing a pre-curved shape to the catheter body (Figure 2).

To have provided the Levin et al catheter device, as modified by the teaching of Brucker et al, with a second lumen for housing a control wire to control the shape of the catheter would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Bednarek et al.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al ('830), Brucker et al ('197) and Bednarek (6,120,500) as applied to claim 23 above, and further in view of the teaching of Swartz et al (6,080,151).

The combination of the Bednarek et al teaching with the Levin et al and the Brucker et al devices has been addressed. While each of these catheters provide a wire connected to the electrode means, there is no express disclosure that the wire is carried through the second lumen (i.e. isolated from the fluid lumen).

The examiner maintains that the passage of wires through various lumens is generally known in the art, and that to have provided the Levin et al or the Brucker et al wire through either lumen (after considering the modification suggested by Bednarek et al) would have been an obvious design consideration. However, Swartz et al is cited as

showing that it is generally known to provide electrode leads through a second lumen to keep the wires separate from the fluid delivery lumen.

To have provided the Levin et al device, as modified by the teachings of Bednarek et al and Brucker et al, with the lead extending through the second lumen to isolate the wire from the fluid lumen would have been an obvious design modification for one of ordinary skill in the art in view of the teaching of Swartz et al.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Brucker et al ('197) or Collins et al ('886) in view of the teaching of Levin et al ('830).

The Brucker et al and Collins et al devices have been addressed previously. Both of these devices have a braided electrode member embedded in the wall of a catheter, but neither specifically discloses the electrode defines a surface that is raised above the outer surface of the catheter shaft.

Also addressed previously is the Levin et al catheter and its teaching of an electrode embedded in the wall of a catheter. In particular, Levin et al teach that it is known to provide the electrode with a surface that is raised above the outer surface of the catheter shaft to facilitate placement against tissue.

To have formed either the Brucker et al or the Collins et al catheter device with an electrode that projects slightly from the outer wall of the catheter to facilitate contact with tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Levin et al.

Claims 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Brucker et al ('197) or Collins et al ('886) and further in view of the teaching of Bednarek et al (6,120,500).

Collins et al and Brucker et al fail to disclose a second lumen for carrying a control wire for shaping the catheter body as recited in these claims.

As addressed in the previous Office action, Bednarek et al discloses another ablation catheter that provides a second lumen (23 - Figure 11) including a control wire (16) for providing a pre-curved shape to the catheter body (Figure 2).

To have provided either the Collins et al catheter device or the Brucker et al, with a second lumen for housing a control wire to control the shape of the catheter would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Bednarek et al.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Collins et al ('886) or Brucker et al ('197) in view of the teaching of Bednarek (6,120,500) as applied to claim 23 above, and further in view of the teaching of Swartz et al (6,080,151).

The combination of the Bednarek et al teaching with the Collins et al and the Brucker et al devices has been addressed. While each of these catheters provide a wire connected to the electrode means, there is no express disclosure that the wire is carried through the second lumen (i.e. isolated from the fluid lumen).

The examiner maintains that the passage of wires through various lumens is generally known in the art, and that to have provided the Collins et al or the Brucker et al wire through either lumen (after considering the modification suggested by Bednarek et al) would have been an obvious design consideration. However, Swartz et al is cited as showing that it is generally known to provide electrode leads through a second lumen to keep the wires separate from the fluid delivery lumen.

To have provided either the Collins et al device or the Brucker et al device, as modified by the teaching of Bednarek et al, with the lead extending through the second lumen to isolate the wire from the fluid lumen would have been an obvious design modification for one of ordinary skill in the art in view of the teaching of Swartz et al.

Response to Arguments

Applicant's arguments filed May 15, 2009 have been fully considered but they are not persuasive.

Brucker Anticipatory Rejection

Regarding claim 33 and the Brucker reference, the applicant asserts that the Brucker braided electrode is not "interposed" in a fixed position between the inner and outer surfaces. Applicant goes on to indicate that the braided electrode of the instant application is sandwiched between the inner and outer surfaces. Applicant goes on to assert that the Brucker electrode is provided on the outer surface of the catheter and that no part of the electrode is sandwiched between the inner and outer surfaces of the catheter.

Initially, the examiner maintains that there is nothing in the claims that requires the electrode to be "sandwiched", and that the term "sandwiched" is more limiting than "interposed". Regarding the surfaces, the examiner maintains that the outer surface of the Brucker device is designated by reference numeral (22) in Figure 16. The electrode (91) is clearly recessed relative to this outer surface such that the electrode surface is flush with the outer surface. The examiner maintains that the electrode (91) is clearly interposed between the outer surface and the inner surface of the catheter body and resides in a recessed portion of the catheter so that the electrode is flush with the outer surface. There is nothing in the claim language that requires the outer surface to cover any portion of the electrode. As such, the examiner maintains the rejection is tenable.

Regarding claim 26 and the Brucker reference, this rejection has been withdrawn in view of applicant's amendments to claim 26.

Collins Anticipatory Rejection

Regarding the Collins reference, applicant asserts that Collins fails to disclose a "fixed" braided electrode means or a braided electrode interposed in a "fixed" position because the braided member expands. Applicant argues that the braided member moves relative to the catheter. The examiner maintains that the claim does not specify that the braided member may not move relative to the catheter. Moreover, applicant's braided member moves relative to the catheter because the distal end of the catheter is movable or bendable as shown in Figures 4A-4C. The examiner maintains that the Collins braided member is fixed relative to the inner and outer members in which it is

sandwiched, or interposed, and thus the Collins device fairly reads on the claim language.

Levin in view of Brucker

With respect to this combination, applicant argues that neither Levin nor Brucker defines an aperture (e.g. an opening) through which the electrode is exposed. The examiner disagrees. As asserted above, the examiner maintains that Brucker do not provide the electrode around the outer surface as posited by applicant, but rather provide the electrode in a recessed portion between the inner and outer surfaces as shown in Figure 16. This recessed portion may be deemed an opening, or an aperture, which exposes the electrode. With regard to Levin, the outer wall must have openings along the length through which the electrode exits in order to be exposed on the outer surface as clearly shown in Figures 3 and 4. The examiner maintains that both Levin and Brucker fairly disclose apertures in the broadest reasonable interpretation of the term, and that the rejection remains tenable.

Regarding claim 14, applicant merely reasserts arguments previously addressed, such as the argument that Collins fails to teach a fixed braided electrode. As asserted above, the examiner maintains the Collins braided electrode is fixed relative to the inner and outer layers, and the rejection of claim 14 remains tenable.

Regarding claim 26, applicant's amendments have given cause for the examiner to reject this claim as being obviated by Levin in view of Brucker, and further in view of Collins (similar to claim 14).

Remaining Dependent Claims (19-24)

Applicant's arguments with respect to claims 19-24 are premised solely on the purported shortcomings of Collins, Levin and Brucker with respect to the limitations of claim 33 (as previously addressed). As asserted above, the examiner maintains the combination of the Brucker teaching with the Levin reference remains a tenable rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
September 16, 2009